Recommendation for the preparation of a quality handbook for radiation oncology

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Die Erstellung dieser Empfehlungen erfolgte im Auftrag vom BAG.
Ces recommandations ont été formulées sur mandat de l'OFSP.
Queste raccomandazioni sono state compilate su incarico dell'UFSP.

SRO Swiss Society for Radiation Oncology

SGSMP SSRPM SSRFM
Schweizerische Gesellschaft für Strahlenbiologie und Medizinische Physik
Société Suisse de Radiobiologie et de Physique Médicale
Società Svizzera di Radiobiologia e di Fisica Medica

SVMTRA / ASTRM
Schweizerische Vereinigung der Fachleute für med. tech. Radiologie
Association suisse des techniciens en radiologie médicale
Associazione svizzera dei tecnici di radiologia medica

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Preamble

In April 2017, the Federal Office of Public Health (FOPH) released the new radiation protection ordinance together with the associated technical ordinances, which formally went active by January 1st, 2018. The Swiss Society of Radiobiology and Medical Physics (SSRMP) launched a working group (RPO2MPP) dealing with the implementation of the radiation protection ordinance (RPO) into medical physics practice (MPP). Based on a workshop in August 2017, several topics were jointly elaborated and prioritized. One of the topics is the requirement to provide a recommendation for the radiation therapy community dealing with the preparation of a quality handbook. The creation of the quality handbook is related to the scope of clinical audits, which have been newly established as a peer review procedure on a national level.

The RPO2MPP working group (chaired by Peter Manser) created an expert sub-group of medical physicists (co-chaired by Thomas Götzfried and Hans Neuenschwander) and discussed the topic intensely with the members of RPO2MPP working group. Members of the Swiss Society for Radiation Oncology (SRO), and the Swiss Society of Radiation Therapists (SVMTRA), were also involved in the creation of this document. The translation into English was done by Nicoletta Lomax.

The boards of the three societies SSRMP, SRO and SVMTRA approved this recommendation in Summer 2018 and thank all the contributors for their important work and their efforts.

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Table of contents

1. Introduction

This document is intended to be used as a guideline for radiotherapy centres in the preparation of a quality handbook (QHB), as required by Article 43 of the Radiation Protection Ordinance (RPO) of 26 April 2017. During a clinical audit according to RPO Article 41, the audited institution must be able to present the QHB. This recommendation should primarily ensure that when creating the QHB, none of the required content is overlooked. It is, therefore, structured in such a way that the individual chapters refer directly to the content mentioned in Article 43. Additional aspects that are specific for radiation oncology are also addressed.

The QHB may be in physical or electronic format. Existing quality management (QM) documents may be referenced. For example, a QHB structure with the items mentioned according to this recommendation could be included in a separate chapter of one's own QM system, pointing to corresponding QM documents.

The QHB as required according to RPO Article 43 does not cover all aspects of a clinical audit as mentioned in RPO Article 41. In particular, an important focus of clinical audits is put on the implementation of proper patient- and staff-related procedures in an institution making use of ionizing radiation. These procedures should be defined and documented as part of the QM-system. The checklist in the appendices of this recommendation is intended to give an idea of the scope and help in the preparation of a clinical audit in radiation oncology.

2. Duties and responsibilities

Recommendations:

- documentation showing the organisation of the radiotherapy centre (organigram);
- documentation of duties, responsibilities and competencies regarding the operation of the facility;
- documentation of duties, responsibilities and competences regarding radiation protection.

Notes:

It is good practice to have job descriptions available for all members of the team, including assignment of duties, responsibilities and competences of the individual employees, in particular if special tasks are allocated. An organigram can be used to help illustrate the structure and responsibilities. A template for a possible organigram of a radiotherapy centre can be found in the appendix.

As a minimum, the following functions should be named and briefly described:

- licence holder;

- radiation protection experts/advisors (for the use of ionizing radiation on patients, for radiation protection of employees and members of the public);
- Clinical Head of Department;
- Head of Medical Physics;
- Head Radiographer (Head RTT);
- person responsible for the QM system (including QHB);
- special tasks of individual employees (e.g. personal dosimetry, training managers for RTTs etc.).

In addition, the deputy for each function should be designated.

3. Equipment used for examination and treatment

Recommendations:

- list of all devices requiring licences;
- documentation of all equipment used in the preparation/planning and implementation of radiotherapy;
- inventory of radioactive sources and relevant documentation.

Notes:

The documentation should include the following items:

- type of device;
- date of installation, acceptance protocol;
- FOPH licence (number, date of issue, expiry date);
- radiation protection plans and calculations;
- service contracts
- instruction manuals;
- regulations regarding training, operation and maintenance necessary for the device.
- most of the abovementioned documents are typically found in the radiation device handbook ("Anlagebuch", "dossier technique"), which can be referenced.

For the sake of completeness and clarity, it is also useful to show the location of the radiation devices, controlled and supervised areas ("Kontroll- und Überwachungsbereiche", "secteurs contrôlés et surveillés") and radioactive sources on a plan of the department.

4. Staff training

Recommendations:

- documentation for the induction of new employees;
- documentation of the education and training status of all employees;
- documentation of the individual radiation protection training of all employees;

- check procedures to ensure that the requirements of the training regulations in radiation protection are met for each employee.

Notes:
Due to the variety of equipment and processes in different radiotherapy centres, careful attention must be paid to the induction of new employees. This should therefore be structured and documented.
Regular internal and external continuing education and training in areas of radiotherapy and radiation protection should be made available.

With regard to radiation protection, the Ordinance on Trainings and Permitted Activities in Radiation Protection regulates the objectives, the requirements and the scope of the training for all staffing groups concerned. The training in radiation protection should therefore be recorded and documented for all relevant employees (doctors, physicists, radiographers, medical practice assistants etc.).

It is advisable to document the status of training, continuing and further education for each employee in a comprehensive manner. The content, the extent and the provider of training and continuing/further education should be documented.

4.1 Physician (Radiation oncologist)

According to Article 40 MedBG/LPMéd, continuing medical education is mandatory for practicing doctors. For radiation oncologists this is regulated by the continuous medical education programme of the Swiss Society for Radiation Oncology (SRO) (last successful access on 17.04.2018: https://www.sro-ssro.ch/continuous-medical-education/general-information/).

The practical training in radiation protection takes place in the context of the postgraduate training as a specialist in radiation oncology at a recognised postgraduate training centre. The extent of continuing education in radiation protection is regulated in the Ordinance on Trainings and Permitted Activities in Radiation Protection (8 teaching units in 5 years).

The radiation oncologist is personally responsible for attending the required training and must be able to show documented evidence of the training at all times.

4.2 Medical Physicist

In order to maintain the professional recognition, the obligatory continuing professional development must be fulfilled in accordance with the guidelines of the SSRMP (last successful

access on 31.12.2018: http://ssrmp.ch/certification-for-medical-physicists/rules/).
Appropriate training in radiation protection is a part of the SSRMP certification process in medical physics. The extent of continuing education in radiation protection is regulated in the Ordinance on Trainings and Permitted Activities in Radiation Protection (8 teaching units in 5 years, the continuing education being subject to recognition). The medical physicist is personally responsible for attending the required training and must be able to show documented evidence of the training at all times.

4.3 Radiographers (RTTs)

The continuing professional development of radiographers (RTTs) is regulated by the radiotherapy centres and may be internal and / or external (e.g. SVMTRA/ASTRM training events).

The practical training in radiation protection takes place whilst qualifying as an RTT. The extent of continuing education in radiation protection for RTTs is regulated in the Ordinance on Trainings and Permitted Activities in Radiation Protection (8 units in 5 years).

The level of qualification, the induction of new staff members and the continuing education of staff members should be documented and the documentation should be continually up-dated.

4.4 Other staff

For other persons (medical practice assistants, nursing staff, technicians etc.), the person responsible for radiation protection must individually determine the extent to which these persons are obliged to undergo training and continuing education in radiation protection. This must be documented accordingly.

5. Justification of the individual application (Indication)

Recommendations:
In this chapter of the QHB, the radiotherapy centre should define:

- the minimum amount of documentation required to make the indication for radiotherapy;
- according to which general guidelines the indication is made;
- specific standard protocols to be used for specific indications, if available;
- with which tumour boards radiation oncology is directly involved;
- with which tumour boards there is a co-operation;

- the requirements of the documentation for making the indication for radiotherapy for each individual patient. As a minimum, this should include the principles on which the indication is based (e.g. guidelines) and, if available, the recommendation made by the tumour board.

In addition, the process of regular review of the standard practices, for example in the context of self-audit, should be documented.

Notes:
When making the indication for radiotherapy treatment, the radiation oncologist should, in general, follow national and international guidelines. The following organisations provide quite comprehensive guidelines:

- DEGRO: https://www.degro.org/ueber-uns/veroeffentlichungen/leitlinien/;
- ASTRO: https://www.astro.org/Clinical-Practice-Statements.aspx;
- NCCN: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

If no guideline exists, the basis for the indication should be documented (evidence from the literature, general or local consensus, personal experience etc.).

Today the majority of all tumour diseases are discussed in tumour boards. The radiation oncologist is required to include recommendations of the tumour board in his considerations and inform the patient of alternative treatment options, if they exist.

In order for important new findings on the efficacy or side-effects of treatment methods to be incorporated into clinical practice, the justification for indications should be regularly reviewed by the radiation oncologist and adapted as necessary.

6. Patient identification and information

Recommendations:

- documentation of measures taken to ensure the correct identification of a patient;
- definition of the scope of documentation for a particular patient and his therapy;
- definition of the procedure when informing the patient of his medical situation and treatment options, as well as the scope of the information given;
- presentation of the circumstances under which treatment is refused (taking into account the medical justification and the patient's wishes).

Notes:
The radiotherapy centre must ensure that all necessary patient data required in making the indication and in the implementation and follow-up of the radiotherapy treatment are collected and updated and also remain available after completion of the treatment.

The data belonging to a patient must be unambiguously marked. A mistake in the patient identity during the treatment, in the aftercare, or within the legally required duration of the data storage, must be excluded.

The patient is usually informed about the indication for radiation therapy and the planned treatment procedure during a consultation with the radiation oncologist. The consultation should be documented, with documentation including as a minimum:

- the explanation of the chances of cure and risks involved in the intended radiotherapy, as well as the prognosis with and without the treatment;
- information about alternative treatments, if any, and their risks;
- the consent of the patient to the prescribed radiation treatment (a patient signature is not required by law);
- the reasoning behind why radiotherapy may be out of the question (from a medical and / or patient perspective).

For a patient to legally consent to treatment, the patient must be sufficiently well informed. In case of dispute, the physician or the hospital must be able to prove that correct and sufficient information was provided. A written documentation outlining the patient consultation/information is, therefore, essential. The nature and extent of information and explanation given to the patient are regulated by the cantonal health laws (see, for example, Article 39 of the Health Law (GesG), Bern). Furthermore, reference may be made to the code of conduct of the Swiss Medical Association (FMH).

It is more straightforward for the patient to be led through a written patient information sheet which can later be reread. For this reason, and also to provide proof in case of a later dispute, it is worth considering the use of a written patient information sheet, to be signed by the patient.

7. Medical treatment instruction (Radiotherapy prescription)

Recommendations:

- definition of the documentation required for the radiotherapy treatment instruction;
- documentation as to which standard protocols are used (dose prescription, tolerance doses etc.);
- definition of the procedure and the documentation requirements in case of deviations from the standard protocols;
- definition of the procedure for the quality assurance of the treatment instruction.

Notes:

The radiotherapy centre must ensure that a radiotherapy treatment instruction is prepared for the individual patient for the intended therapy. This must be defined and documented by

a radiation oncologist before the first irradiation. The documentation may be kept electronically and should contain the following information (see Appendix 5 of the Accelerator Ordinance):

- date of issue of the radiotherapy prescription and identification of the responsible physician;
- information regarding the identity of the patient;
- medical history;
- special issues such as pacemaker, defibrillator, previous radiotherapy treatment dose etc.;
- brief description of the disease;
- goal and treatment intent of radiation treatment;
- standard protocols according to guidelines, e.g. NCCN guidelines (including single fraction dose, total dose and fractionation);
- description of target volumes and regions at risk;
- tolerance doses for risk structures according to guidelines, e.g. QUANTEC;
- selected treatment plan;
- description of planned combined therapies, for example hyperthermia and chemotherapy.

Subsequent changes must be justified and documented.

8. Patient specific irradiation instruction

Recommendations:

- definition of the requirements for the documentation of the irradiation instruction;
- definition of the criteria for the acceptance of a treatment plan taking into account the individual treatment instruction;
- definition of the procedure for the quality assurance of the individual irradiation instruction.

Notes:

The radiotherapy centre must ensure that a patient-specific irradiation instruction is prepared on the basis of individual treatment planning in order to implement the prescribed medical treatment instruction. The patient specific irradiation instruction contains all the information needed to carry out the irradiation, in particular those for patient positioning and set-up and those pertaining to the accelerator (or irradiation unit) settings. The patient-specific irradiation instructions can be kept electronically and should contain the following information (see Appendix 5 of the BeV/OrAc):

- date and identification of persons responsible for planning the treatment (doctor, medical physicist, dosimetrist);
- information regarding the identity of the patient;

- treatment planning documents (medical imaging, target volumes, organs at risk, previous irradiation dose etc.);
- treatment plan with dose distribution;
- information on measures taken to verify the treatment (imaging, in vivo dosimetry, laboratory tests etc.);
- information about the patient positioning and fixation and about special procedures (e.g. respiratory control, surface monitoring, transponder tracking etc.)
- particulars of the radiation delivery (in particular number of fields, number of fractions per day and total number of fractions, intervals between fractions);
- physical radiation parameters (in particular irradiation technique, type of radiation, radiation energy, individual and total doses to the target volumes and organs at risk, monitor units / treatment time);
- geometric parameters of the irradiation device and the treatment couch (in particular field size, angles, positional parameters, focus-skin distance), as well as instructions for positioning and fixation of the patient;
- field-specific accessories (wedge filters, shielding blocks, compensators, multi-leaf collimators etc.).

If changes are made to the treatment plan, the patient specific treatment instructions must be updated accordingly.

9. Documentation of the treatment

Recommendations:

- definition of the minimum requirements for the documentation of the radiotherapy treatment in the patient chart;
- definition of the minimum requirements for the documentation of the treatment in reports sent to referring physicians and other physicians involved in the patient treatment.

Notes:

All parameters of the treatment, which are necessary in order to reconstruct the delivery of the radiotherapy treatment and the applied dose, must be documented and accessible at all times. The radiotherapy centre must take suitable measures to ensure that a dose reconstruction of the treatment is possible. Information on minimum information for the documentation of irradiation can be found, for example, in the BeV/OrAc (Appendix 5), the RöV/OrX (Article 20) and the MeQV/OSRM (Article 5). The documentation may be stored electronically. Persons who carry out the irradiation must be able to access and print this data at any time.

Essential information and documents are:

- identification of the physician responsible for the radiotherapy treatment;

- medical treatment instruction (see chapter 7 of this document);
- patient-specific irradiation instructions (see chapter 8 of this document);
- proof of irradiation according to Appendix 5 BEV/OrAc.

Documentation should also include instructions on the method of informing the referring physicians and other physicians involved with the patient treatment about the radiotherapy treatment delivered.

Information required in a treatment report (to referring and other physicians):

- patient administrative data;
- list of diagnoses / symptoms and progression of the disease;
- physician to receive the results;
- treating doctor, including any supervisor, contact details for enquiries;
- date and duration of radiotherapy;
- description of the radiotherapy delivered (volume, dose, fractionation, mention of any special procedures, e.g. stereotactic, respiratory control etc.);
- description of the outcome, including any side effects or complications and the therapeutic measures taken to deal with such complications;
- potential side effects which may be expected, with instructions for dealing with them.

10. Treatment evaluation (Follow-up / aftercare)

Recommendations:

- documentation of the follow-up program;
- description of the type and extent of the evaluation of clinical outcome (collection and analysis of the data).

Notes:

At the end of the treatment there should be a final consultation between the doctor and patient and a final report should be sent to the referring physician. Following this a follow-up / aftercare programme should be in place. Aftercare should include a detailed recording and documentation of all outcomes of the radiotherapy treatment. The type of aftercare is usually disease dependent.

The process of follow-up or aftercare must be documented, for example:

- contact person or doctor responsible for the treatment;
- type and frequency of follow-up checks:
  - Follow-up consultations when, for which patients?
  - internal follow-up checks, enquiries with referring physician, external reports;
- planning and structure of follow-up;

- documentation and recording of the outcomes of the disease / treatment, for example:
    - quality of life;
    - support (psycho-oncology, self-help group, cancer counselling);

11. Data management

Recommendations:

Documentation of processes for:

- data control and transfer (including image documentation) to referring doctors or others upon justified requests;
- data protection;
- data backup;
- archiving of data.

Notes:

Personal medical data is subject to general data protection and medical confidentiality requirements. The records may be stored in electronic format, as long as the requirements of the relevant data protection laws are met (Federal Law on Data Protection (DSG/LPD), cantonal data protection laws). The data required for the reconstruction of radiotherapy treatments must be accessible at any time during the obligatory period for storage (radiotherapy: 20 years) and must be accessible in an unmodified state. Damage caused by natural hazards must also be ensured against, for example by redundant storage of data.

12. Quality assurance (QA)

Recommendations:

- documentation of equipment acceptance and commissioning (to be used as a reference for the QA program);
- documentation of the QA programs of all devices and technical equipment (for both the manufacturer and the operator/user);
- documentation and archiving of quality assurance results;
- documentation of the processes and measures for dealing with equipment malfunctions and procedures in place in case the tolerance limits are exceeded (recording, communication, tracking etc.);
- documentation of staff responsible for QA and rules regarding delegation and training of QA work.

Notes:

The radiotherapy centre must take measures to maintain the safety and functionality of all equipment required for the preparation and delivery of radiotherapy treatment. Servicing (inspection, maintenance and repair) and quality control measures must be documented.
Test methods, frequencies, tolerances and intervention thresholds are based on guidelines and recommendations published by the FOPH and the SSRMP, backed up where necessary by current scientific and technical literature.

13. Self-Evaluation / Continuous Improvement Process (CIP)

Recommendations:

- methods for self-audit of processes and measures for furthering quality must be defined and documented;
- process of implementing measures resulting from the self-audit must be documented;
- means of dealing with incidents, irregularities and deviations from intended procedure must be documented.
- For self-evaluation the checklist for clinical audits (Appendix 14.1) should be used.
- A responsible person has to be defined.

Notes:

The QM system and its procedures should be reviewed at least annually in order to obtain objective criteria for assessing the effectiveness of all aspects of the checks to be carried out ("internal audit").
Different methods can be used:

- regular evaluation of the procedures by the various professional groups involved;
- identification and review of the nature and extent of errors that have occurred (which must be documented in accordance with Article 50 RPO), as well as measures taken as a consequence in order to make good the error, follow up on it and ensure a similar error is avoided in the future.
- Critical Incident Reporting System (CIRS);
- system for the anonymous capture of all varieties of errors and incidents.
- therapy outcome;
- patient satisfaction, for example with regard to waiting time, atmosphere, adequate information;
- feedback from referring physicians.

Considerations as a result of external audits:

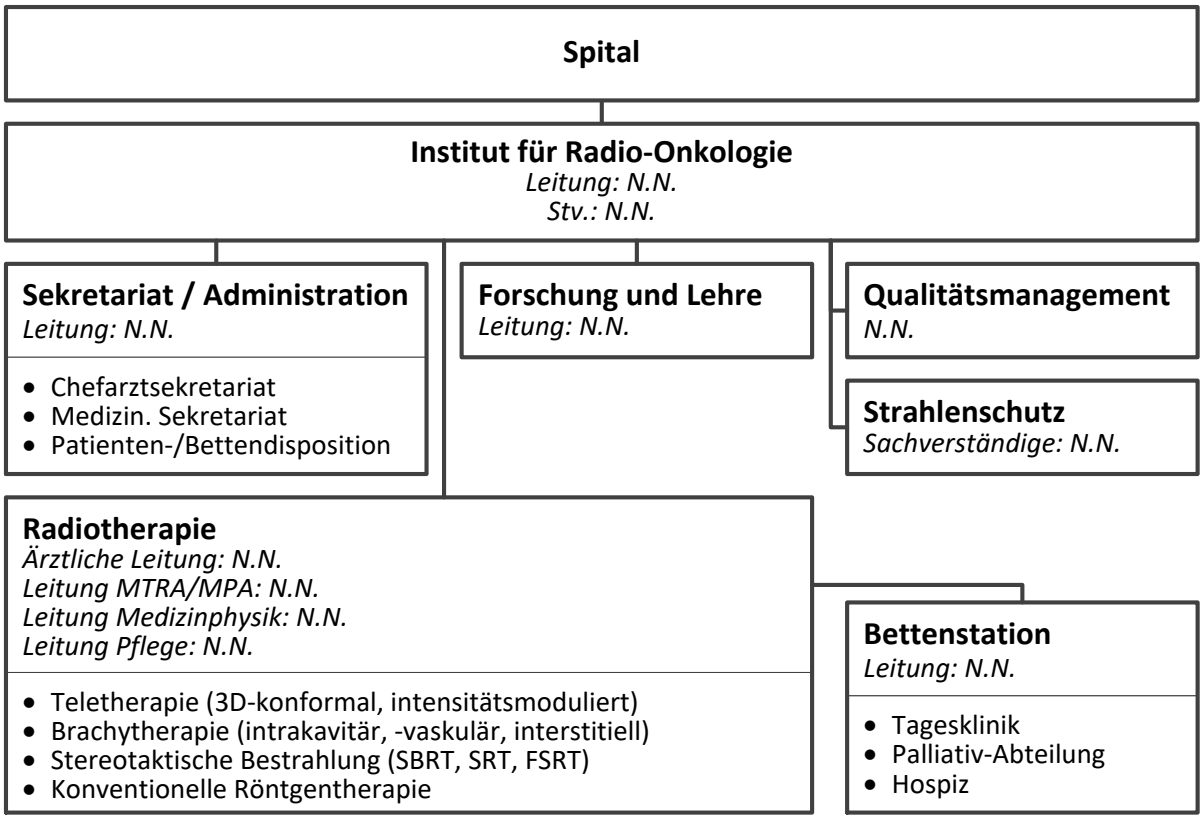
- results of FOPH audits;
- results of clinical audits;
- results of other external audits, e.g. as part of certifications;
- results of SSRMP dosimetry intercomparison.

14. Appendix

14.1 Checklist for clinical audits (next page)

14.2 Example ‘Audit plan’ (next pages)

14.3 Example organigram of a radiotherapy centre



14.4 List of abbreviations

ASTRM	Association Suisse des techniciens en radiologie médicale
ASTRO	American Society for Radiation Oncology
BeV	Beschleunigerverordnung
CIP	Continuous improvement process
CIRS	Critical incident reporting system
DEGRO	Deutsche Gesellschaft für Radioonkologie
DSG	Bundesgesetz über den Datenschutz
FMH	Foederatio Medicorum Helveticorum (Swiss Medical Association)
FOPH	Federal Office of Public Health
GesG	Gesundheitsgesetz Kt. Bern
LPD	Loi fédérale sur la protection des données
LPMéd	Loi sur les professions médicales
MedBG	Medizinalberufegesetz
MeQV	Verordnung über den Umgang mit geschlossenen radioaktiven Quellen in der Medizin
NCCN	National Comprehensive Cancer Network
OrAc	Ordonnance sur les accélérateurs
ORaP	Ordonnance sur la radioprotection
OrX	Ordonnance sur les rayons X
OSRM	Ordonnance sur l'utilisation de sources radioactives scellées en médecine
QA	Quality assurance
QHB	Quality handbook
QM	Quality management
QUANTEC	Quantitative Analysis of Normal Tissue Effects in the Clinic
RöV	Röntgenverordnung
RPO	Radiological Protection Ordinance
RTT	Radiation Therapist ("MTRA")
SRO	Swiss Society for Radiation Oncology
SSRMP	Swiss Society of Radiobiology and Medical Physics
StSV	Strahlenschutzverordnung
SVMTRA	Schweizerische Vereinigung der Fachleute für med. tech. Radiologie

Authorisation Number	**Institute of Radiotherapy:**	**-** **.**

Date of Clinical Audit:

Auditors:	**Who is leading the audit?**
Radiation Oncologist SRO:	☐
Medical Physicist SGSMP:	☐
Radiotherapist SVMTRA:	☐
In addition:	☐

Participants of the audited institution:

Radiation Oncologist/s:

Medical Physicist/s:

Radiotherapist/s:

In addition:

Abbreviations/Explanations:

Y: Yes
N: No
N/A: not applicable

IMPORTANT: If items are not evaluated, please state this clearly under 'Comments'

PLEASE, NOTE THAT ANSWERS/FINDINGS ARE CONFIDENTIAL!

1. Patient identification:

		Y N NA	Comments
1.	The patient identification process is clear and documented in the QM manual.	☐☐☐	
1.1.	How is a patient identified at RT start and on a daily basis? (multiple answers possible)		
1.1.1	Gender?	☐☐☐	
1.1.2	Date of birth?	☐☐☐	
1.1.3	Patient identification number?	☐☐☐	
1.1.4	Photograph ID (face)?	☐☐☐	
1.1.5	Photograph of treatment fields/patient positioning?	☐☐☐	
1.1.6	Others (please specify under ‚Comments')		

2. Tumor diagnosis and staging:

		Y N NA	Comments
2.	Tumor diagnosis and staging is complete for treatment decision.	☐☐☐	
2.1.	Clinical history is documented in the patient chart.	☐☐☐	
2.2.	Physical examination (eg. tumor region) is documented in the patient chart.	☐☐☐	
2.3.	Pathology reports are in the patient chart.	☐☐☐	
2.4.	Relevant radiological reports are in the patient chart.	☐☐☐	
2.5.	Relevant laboratory reports are in the patient chart.	☐☐☐	
2.6.	Reports of relevant endoscopic procedures are in the patient chart.	☐☐☐	
2.7.	Tumor stage (eg. TNM, FIGO..) is documented in the patient chart.	☐☐☐	
2.8.	Performance status (eg. WHO, Karnofsky, ECOG) is documented in the patient chart.	☐☐☐	

3. RT indication and treatment decision:

		Y N NA	Comments
3.	RT indication and treatment decision are reasonable and justified.	☐☐☐	
3.1.	Curative treatment decision is based upon interdisciplinary tumor boards.	☐☐☐	
3.2.	Palliative treatment decision is based upon interdisciplinary tumor boards.	☐☐☐	
3.3.	Are written treatment protocols available for most common clinical situations (CS)?	☐☐☐	
3.3.1	If yes, please specify CS (or tumor entities) under 'Comments'		
3.4.	Are national/international guidelines in use?	☐☐☐	
3.4.1	If yes, please specify under 'Comments'		
3.5.	Are treatment protocols regularly reviewed?	☐☐☐	
3.5.1	If yes, please specify the frequency of review under 'Comments'		
3.6.	Are benefits and risks explained to the patient?	☐☐☐	
3.6.1	If yes, please specify 'How?' under ‚Comments'		
3.7.	Does a formal consent and agreement form exist in the patient chart?	☐☐☐	
3.7.1	Does the patient receive a copy?	☐☐☐	

4. Organisation:

		Y N NA	Comments
4.1.	A quality management (QM) documentation is available.	☐☐☐	
4.1.1	The QM documentation is adapted at least once a year.	☐☐☐	
4.1.2	If yes, please specify the time intervall under ‚Comments'		
4.2.	The responsibilities of each co-worker are clear and documented in the QM manual.	☐☐☐	
4.3.	The coverage for absences of radiation oncologist/medical physicist/RTT is secured.	☐☐☐	
4.4.	There is a 24 hour service available in case of emergencies (written 'Dienstplan'/duty roster for MD available).	☐☐☐	
4.5.	Is there a possibility for the patient to have an appointment with a nurse?	☐☐☐	
4.6.	Is there a possibility for the patient to have an appointment with a medical physicist?	☐☐☐	
4.7.	Is there a possibility for the patient to have an appointment with a psychooncologist?	☐☐☐	
4.8.	Continuous education of co-workers is guaranteed.	☐☐☐	
4.8.1	If yes, please specify under comments		

5. Dose prescription:

		Y N NA	Comments
5.1.	The process of ‚dose prescription' is clear.	☐☐☐	
5.2.	The process of ‚dose prescription' is documented in the QM manual.	☐☐☐	
5.3.	All necessary RT dose informations (eg. single dose, total dose, fractionation scheme, beam modality/energy, bolus etc.) are documented.	☐☐☐	
5.3.1	Please describe under ‚Comments', how this is done.		
5.4.	The prescription is signed by the radiation oncologist.	☐☐☐	
5.4.1	The prescription is double-checked (4-eyes-principle).	☐☐☐	
5.5.	The process of 'treatment alterations' is clearly defined.	☐☐☐	
5.6.	Please describe under 'Comments', how treatment alterations will be handled.		

6. Patient positioning/immobilization; data acquisition

		Y N NA	Comments
6.1.	The process of ‚patient positioning/immobilization' is clear.	☐☐☐	
6.2.	The process of ‚patient positioning/immobilization' is documented in the QM manual.	☐☐☐	
6.3.	In patients with planning CT the scan area is defined by the responsible radiation oncologist.	☐☐☐	
6.4.	Appropriate immobilization devices are available.	☐☐☐	
6.4.1	Individual immobilization and setup support has to be documented	☐☐☐	
6.4.2	If yes, please specify under 'Comments'		
6.5.	Standard operating procedures (SOPs) for patient positioning/immobilization for most common clinical situations are available and in the QM manual.	☐☐☐	
6.5.1	If yes, please specify under 'Comments'		
6.6.	Patients for stereotactic radiotherapy/radiosurgery have a separate SOP for positioning/immobilization	☐☐☐	
6.6.1	If yes, please specify differerences under 'Comments'		
6.7.	The field(skin) marking procedure/process is clear.	☐☐☐	
6.7.1	How are fields marked? Please specify under ‚Comments'		
6.7.2	How are marks maintained during treatment? Please specify under ‚Comments'		
6.7.3	How are marks documented for RTTs? Please specify under ‚Comments'		
6.8.	The field(skin) marking procedure/process is documented in the QM manual.	☐☐☐	
6.9.	The simulation is done by ☐ fluoroscopic simulator ☐ CT simulator ☐ virtual sim		
6.9.1	What has been done to optimize patient dose? Please specify under 'Comments'		
6.9.2	Are dose optimisation protocols available?	☐☐☐	
6.9.3	An exposure chart (kV and mAs) is available.	☐☐☐	
6.10.	The simulation process is clear.	☐☐☐	
6.11.	The simulation process is documented in the QM manual.	☐☐☐	
6.12.	The data transfer from imaging to planning is clear.	☐☐☐	
6.12.1	The data transfer is ☐manual ☐ automatic		

6.13.	The institute has a CT dedicated for planning.	☐☐☐	
6.14.	There is a possibility for 4D CT scans.	☐☐☐	
6.14.1	If yes, please specify under ‘Comments’ for which clinical situations 4D CT scans are used.		

7. Treatment planning:

		Y N NA	Comments
7.1.	The process of ‚treatment planning' is clear.	☐☐☐	
7.2.	The process of ‚treatment planning' is documented in the QM manual.	☐☐☐	
7.3.	Treatment planning guidelines/protocols for the most common clinical situations (CS) are available.	☐☐☐	
7.3.1	If yes, please specify under 'Comments' for which CS		
7.4.	According to treatment planning, are national/international guidelines in use?	☐☐☐	
7.4.1	If yes, please specify under 'Comments'		
7.5.	Tumor volume delineation will be validated by the radiation oncologist.	☐☐☐	
7.5.1	Are tumor volumes delineated for curative (local radical) RT?	☐☐☐	
7.5.2	Are tumor volumes delineated for palliative RT?	☐☐☐	
7.5.3	Following target volumes (ICRU50&62) are delineated: **PTV only** (please specify under 'Comments' situations where no PTV is delineated) **GTV/CTV** in appropriate situations (please specify under 'Comments')	PTV only ☐☐☐ GTV/CTV ☐☐☐	
7.6.	OAR are done or checked by the radiation oncologist.	☐☐☐	
7.7.	Additional images (MRI, PET-CT…) are fusioned for target definition.	☐☐☐	
7.7.1	If yes, please specify clinical situations under 'Comments'		
7.8.	The process of 'image fusion' is clear and in the QM manual.	☐☐☐	
7.9.	Dose constraints for organs-at-risk are used for planning/plan comparison. Please specify under 'Comments' for the most common clinical situations or give reference of source data.	☐☐☐	
7.10.	Please specify for which clinical situations a 2D/2D+ or manual dose calculation will be used		
7.11.	The treatment plan is validated. Please specify under 'Comments' 'by whom' and 'how'	☐☐☐	
7.12.	Is there a planning review meeting?	☐☐☐	
7.12.1	If yes, please specify under 'Comments'.		
7.13.	The process of data transfer from planning to delivery is clear.	☐☐☐	
7.14.	The process of data transfer from planning to delivery is documented in the QM manual.	☐☐☐	

8. Mould room and beam modification devices:

		Y N NA	Comments
8.1.	Are standard blocks in use?	☐☐☐	
8.2.	The process of ‘block production’ is clear.	☐☐☐	
8.3.	The process of ‚block production‘ is documented in the QM manual.	☐☐☐	
8.4.	Please specify under ‘Comments’ for which clinical situations blocks are used.		
8.5.	How are blocks designed? Please specify under ‘Comments’.		
8.6.	How are blocks verified? Please specify under ‘Comments’.		
8.7.	Are ‘beam modifiers’ other than blocks or MLC used? If yes, please specify under ‘Comments’.	☐☐☐	

9. Treatment delivery:

		Y N NA	Comments
9.1.	The process of 'treatment delivery' is clear.	☐☐☐	
9.1.1	The process of 'treatment delivery' is documented in the QM manual.	☐☐☐	
9.1.2	Who is present during the first RT? Please specify		
9.1.3.	How many RTTs are working on a linear accelera-tor?	Number:	
9.2.	The process of patient positioning at the treatment machine is clear.	☐☐☐	
9.2.1	How will it be secured that positioning for treatment is identical with planning? Please specify		
9.3.	Is IGRT used?	☐☐☐	
9.3.1	Is there a protocol for IGRT practice/use?	☐☐☐	
9.3.2	Cone-beam CTs are performed. If yes, please specify under 'Comments' for which CS		
9.4.	The process of respiratory-gated treatments is clear.	☐☐☐	
9.5.	How will the data transfer from planning to the treatment machine be secured? Please specify		
9.6.	The process of in-vivo-dosimetry is clear.	☐☐☐	
9.6.1	If done, in-vivo-dosimetry is checked by a medical physicist.	☐☐☐	
9.6.2	In-vivo-dosimetry is performed. If yes, please spec-ify under 'Comments' for which CS	☐☐☐	
9.7.	Verification images are checked by a radiation oncologist.	☐☐☐	
9.8.	There are clinical controls by a radiation oncologist during the treatment phase.	☐☐☐	
9.8.1	If yes, please specify frequency and circumstances of controls under ‚Comments'		
9.9.	Documentation of side effects is standardized.	☐☐☐	
9.9.1	If yes, please specify scoring system under 'Com-ments'		
9.10.	Is there a review of the applied dose during and at the end of the radiotherapy? If yes, how will this be done? Please specify under 'Comments'	☐☐☐	
9.11.	The documentation of the RT will be stored for 20 years.	☐☐☐	
9.12.	Regular follow-up checks will be done in patients with a curative intent.	☐☐☐	
9.12.1	If yes, please specify under 'Comments'		
9.13.	The process of an emergency irradiation is clear.	☐☐☐	

10. Institutional and device-specific QA:

		Y N NA	Comments
10.1.	Responsibilities for QA are clearly defined.	☐☐☐	
10.2.	The QA of the linac is according to SGSMP recommendation no 11	☐☐☐	
10.3.	The process of QA for diagnostic modalities (eg. CT) is clear.	☐☐☐	
10.4.	Are doses of diagnostic procedures documented and integrated into the prescribed RT dose?	☐☐☐	
10.5.	Is there additional QA for special RT techniques?	☐☐☐	
10.5.1	If yes, please specify under 'Comments'		
10.6.	In case of modulated/ special RT techniques, is there a patient-specific QA?	☐☐☐	
10.6.1	If yes, please specify under 'Comments'		
10.7.	The process is clearly defined, what to be done if QA measurements are out of tolerance.	☐☐☐	
10.8.	How is QA itself controlled? Please specify under Comments'		
10.9.	Is there a QA for the RT planning system?	☐☐☐	
10.10.	The institution takes part in the yearly dosimetry intercomparison of SGSMP or another dosimetry audit.	☐☐☐	
10.11.	QA procedures are documented in the QA manual.	☐☐☐	

11. Critical incidents:

		Y N NA	Comments
11.1.	There is a critical incident reporting system (CIRS) in place.	☐☐☐	
11.1.1.	If yes, please specify under ‚Comments' which system is used		
11.2.	How will critical incidents be handled within the institution? Please specify under 'Comments'		
11.3.	How many incidents on which severity level have been reported last year?	Number:	
11.4.	The responsibilities in reporting critical incidents are clear.	☐☐☐	
11.5.	An institutional review process of critical incidents is in place.	☐☐☐	
11.5.1.	If yes, please specify the process under 'Comments'.		
11.6.	Have all institutional co-workers access to the CIRS?	☐☐☐	
11.7.	Will registrable incidents be reported to the BAG? (Does the institution know, which incidents are registrable?)	☐☐☐	
11.8.	Which devices for radiation protection are in use?		
11.9.	The process of a medical emergency is clear.	☐☐☐	

12. Brachytherapy: (☐ not applicable)

HDR Brachytherapy (☐ not applicable)		Y N NA	Comments
12.1.	Please specify under comments for what organ site(s) HDR BT is used (eg. GYN, H&N, GI, Prostate, Breast, Lung, Skin, Soft tissue…)		
12.2.	The process in case of emergency inside the HDR suite/op theatre (radioactive source handling and patient) is clear	☐☐☐	
12.2.1.	The process in case of emergency inside the HDR suite/op theatre (radioactive source handling and patient) is documented in the QM manual	☐☐☐	
12.3.	The process in case of emergency outside an the HDR suite/op theatre (personnel) is clear	☐☐☐	
12.3.1.	The process in case of emergency outside the HDR suite/op theatre (personnel) is documented in the QM manual	☐☐☐	
12.4.	The process for repeated safety drills for HDR are clear	☐☐☐	
12.4.1.	safety drills are repeated regularly and include practical exercises.	☐☐☐	
12.5.	The process of 'treatment delivery' for interstitial HDR brachytherapy is clear	☐☐☐	
12.5.1.	The process of 'treatment delivery' for interstitial HDR brachytherapy is documented in the QM manual	☐☐☐	
12.6.	The process of 'treatment delivery' for intracavitary HDR brachytherapy is clear	☐☐☐	
12.6.1.	The process of 'treatment delivery' for intracavitary HDR brachytherapy is documented in the QM manual	☐☐☐	
12.7.	Please specify positioning control in different BT applications under comments		
12.8.	The process for anesthesia/analgesia is clear	☐☐☐	
12.8.1.	Please specify under comments for what organ site(s) anesthesia/analgesia is used (eg. GYN, H&N, GI, Prostate, Breast, Lung, Skin, Soft tissue…)		
12.9.	The process for dose prescription/calculation is clear and documented in the QM manual	☐☐☐	
12.9.1.	What prescription guidelines are used (ICRU etc), please specify under comments		
12.9.2.	Does the responsible physician see and sign the dose calculation?	☐☐☐	
12.9.3	Does the responsible physicist see and sign the dose calculation?	☐☐☐	
12.9.4.	Is there a cross check of the dose calculation?	☐☐☐	

12.10.	The process for in-vivo dosimetry is clear, if used	☐☐☐	
12.10.1.	If done, in-vivo-dosimetry is checked by a medical physicist	☐☐☐	
12.10.2.	If in-vivo-dosimetry is done, please specify for what organ site(s) under comments		
12.11.	The process for reporting and recording the HDR brachytherapy treatment is clear	☐☐☐	
12.12.	The process for ensuring coordination in treatment dosimetry and scheduling between LDR brachytherapy and teletherapy is clear, if used	☐☐☐	
12.13.	The process for maintaining aseptic conditions for the insertion of needles, applicators/ cylinders in HDR brachytherapy is clear	☐☐☐	

LDR Brachytherapy (☐ not applicable)		Y N NA	Comments
12.14.	Please specify under comments for what organ site(s) LDR BT is used		
12.15.	The process in case of emergency inside the LDR suite/op theatre (radioactive source handling, personnel and patient) is clear	☐☐☐	
12.16.	The process in case of emergency inside the LDR suite/op theatre (radioactive source handling, personnel and patient) is documented in the QM manual	☐☐☐	
12.17.	The process of 'treatment delivery' for interstitial LDR brachytherapy is clear	☐☐☐	
12.18.	The process of 'treatment delivery' for interstitial LDR brachytherapy is documented in the QM manual	☐☐☐	
12.19.	How is positioning control done? Please specify under comments		
12.20.	The process for dose prescription/calculation is clear	☐☐☐	
12.20.1.	Does the responsible physician see and sign the dose calculation?	☐☐☐	
12.20.2.	Does the responsible physicist see and sign the dose calculation?	☐☐☐	
12.20.3.	Is there cross checking of the dose calculation?	☐☐☐	
12.21.	What prescription guidelines are used (ICRU etc), please specify under comments		
12.22.	The process for in-vivo dosimetry is clear, if used	☐☐☐	
12.22.1.	If done, in-vivo-dosimetry is checked by a medical physicist	☐☐☐	
12.22.2.	If in-vivo-dosimetry is done, please specify for what organ site(s) under comments		
12.23.	The procedure for ensuring there is no source loss during treatment is clear	☐☐☐	
12.24.	The process for reporting and recording the LDR brachytherapy treatment is clear	☐☐☐	
12.25	The process for ensuring coordination in treatment dosimetry and scheduling between LDR brachytherapy and teletherapy is clear, if used	☐☐☐	
12.26.	The process for aseptic conditions for the insertion of needles, applicators/cylinders in LDR brachytherapy is clear	☐☐☐	

Plan d'audit pour ‚xy'

Informations générales	
Type d'audit:	« Audit clinique »: audit sous la forme d'un « peer review », c'est-à-dire une évaluation effectuée par des pairs
Date de l'audit:	
Langue de l'audit:	*Français*
Buts de l'audit:	Minimisation des examens et des traitements médicaux injustifiés utilisant des rayonnements ionisants et optimisation des processus et des ressources.

Team d'audit	
Lead-auditeur*:	
Auditeur* 2:	
Auditeur* 3:	

Les textes italiques représentent des exemples.
*: le masculin générique est uniquement utilisé pour améliorer la fluidité de lecture. Il représente donc tout genre.

Plan d'audit				
Heure	**Thème**	**Participants**	**Lieu**	**Auditeur**
09:15 – 09:40	Mot de bienvenue et présentation de l'institution (budget, membres du personnel, techniques et appareils, structures des locaux, tâches en matière de formations de base, postgrade et continue, structures de l'hôpital)	*Tous les participants à l'audit et autres personnes intéressées*	*Salle de séance*	Tous
09:45 – 11:00	Protocoles de planification CT Aides au positionnement	*TRM (responsable)*	*A son poste de travail*	TRM
09:45 – 11:00	Traitement de l'imagerie Transmission des données Fusion d'image	*Physicien médical (en chef), (informaticien)*		Physicien médical
09:45 – 11:00	Protocoles de traitement Définition des structures dans le système de planification Prescriptions concernant les doses (valeurs seuil)	*Radio-oncologue (en chef)*		Médecin
11:05 – 12:10	Planification – généralités Discussion de la planification : concepts et répartition des tâches	*TRM, Physicien médical, médecin*	*Salle de séance*	Tous
12:15 – 12:45	Réunion des auditeurs	-	*Salle de séance*	Tous
12:45 – 13:30	Repas	*Si intéressé*		Tous
13:30 – 14:15	Inspection de clinique (policlinique, brachythérapie, radiothérapie conventionnelle, LINAC)	*Accompagnant*		Tous

14:20 – 15:00	LINAC : positionnement Contrôles du positionnement incluant la radiothérapie asservie à la respiration (gating) Gestion des patients Dotation en personnel	*TRM*	*A son poste de travail*	MTRA
14:20 – 15:00	LINAC : instruments AQ Méthodes de mesure Dosimétrie in vivo	*Physicien médical*		Physicien médical
14:20 – 15:00	LINAC : prise en charge des patients Utilisation / processus en matière de navigation Thérapie de soutien	*Médecin*		Médecin
15:00 – 15:30	CIRS et gestion des urgences	*TRM, physicien médical, médecin*	*Salle de séance*	Tous
15:30 – 16:30	Réunion des auditeurs	-	*Salle de séance*	Tous
16:30 – 17:15	Réunion finale	*Toutes les personnes impliquées*	*Salle de séance*	Tous